Dementia Golf Study

Research Protocol

Rationale

Dementia is a broad term used when the brain has been damaged by a certain disease or condition. There are several different conditions grouped under this umbrella term, such as Alzheimer's disease, vascular dementia and fronto-temporal dementia Prince, 2013 #4228}. The Alzheimer's Society describes dementia as a 'set of symptoms that may include memory loss and difficulties with thinking, problem solving and language' (Alzheimer's Society 2016).

Current funding and research is being targeted at a cure and prevention of dementia, but not for coping or living with dementia. In 2014, then Prime Minister David Cameron announced they were pushing to find new drugs to slow the rate of dementia with the hope of developing a cure by 2025 (Department of Health and Prime Minister's Office, 10 Downing Street, 2014). Last year, up to £150 million pounds was pledged to the UK's first Dementia Research Institute, which would investigate new diagnostic tests and tackle disease progression (Primer Minister's Office 2014). However, there is a lack of research or effort to make those living with dementia lives easier.

Research has highlighted the benefits for people with dementia of taking part in exercise programmes (Forbes, Forbes et al. 2015). For instance, participation in a walking programme has been shown to slow down the rate of cognitive decline (Venturelli, Scarsini et al. 2011). Likewise, a combined aerobic and strength training programme was shown to delay cognitive and motor decline (Bossers, van der Woude et al. 2015). There could also be benefits related to the quality of life of people with dementia (Barnes, Mehling et al. 2015). Participation in physical activity can also decrease behavioural and psychological symptoms of dementia (Fleiner, Leucht et al. 2017). In addition to direct befits of physical activity on dementia, physical activity also reduces the risk of other health problems such as cardiovascular disease (Woodcock, Franco et al. 2011). Physical activity programmes could also offer some benefits for informal caregivers, particularly if the activity is of sufficient duration to allow some respite from their duties as caregivers.

One activity that seems likely to be of benefit to both people with dementia and their caregivers is golf, which has been shown to have many benefits for health and wellbeing of participants (Murray, Daines et al. 2017). Indeed, golf could be one of the best choices for people with dementia as it combines several desirable elements in a physical activity programme. Firstly, it is a typical everyday activity, and is therefore unlikely to be perceived as an activity that must be performed because someone has dementia, and would therefore have no stigma associated with it. It is also an activity that is popular throughout the UK, and is one of the activities that is missed by people when they feel unable to continue due to a

worsening of their condition. Studies have shown that outdoor activities are greatly missed, with people with wising to be able to perform such activities again (Olsson, Lampic et al. 2013). Golf also has an important social element, not to mention being cognitively challenging due to the requirement to judge distance, slope, wind, and ground conditions. However, unlike other sports, golf does not have a reaction-time component that would render it too difficult to perform for people with dementia, as their condition worsens. Golf is also practiced outdoors, which is another desirable element of activities for people with dementia. Indeed, some activities proposed for people with dementia include ecotherapy as a means of improving quality of life in people with dementia. Being outdoors has also been shown to be a facilitator taking part in physical activity (Cedervall and Åberg 2010). Finally, the length of time that golf sessions last for due to the slower pace of the game, means that informal caregivers would be able to have a potential respite from care.

Although no studies have been published on the effect of golf on people living with dementia, a pilot study has been carried out at the Lincoln Golf Centre that has shown very promising results. This initiative was started in October 2015 and can accommodate six golfers at each session. The sessions last for three hours every Thursday, with the qualitative reports showing that golfers enjoy the activity, while their caregivers also appreciate the service. Some of the comments made by caregivers include:

> *"I can't get him to a day centre but I can't stop him coming here."*

> *"He's happier and he's more relaxed so I am more relaxed. It's priceless from my point of view to see him happy and doing something as he was always so active."*

> *"The best way of describing it is that it makes him buoyant, he lights up when he comes here, it brings him alive again."*

In conclusion, it is expected that playing golf will improve physical function and quality of life, while their caregivers will have a decreased burden.

Methods

Research design

The project will be a randomised controlled trial with a partial crossover. Each condition will be followed for eight weeks, with the crossover occurring after eight weeks. Participants will be tested before and after each condition, with a total of three tests per participant. The tests will cover physical function, physical activity level, cognitive function, and quality of life. The caregivers will provide information related to quality of life and psychopathology in dementia of the person they care for, as well as their own quality of life. Full details of the tests to be used are provided in the measurement technique section below. The experimental design is shown in Figure 1.

There will be two 150-min sessions each week, starting with 30 minutes socialising, then 90 minutes playing golf, then 30 minutes socialising. The golf sessions will progress from putting, to chipping, and then a full swing, with sessions taking place on a nine-hole golf course. There will also be an interview with the PWD and their caregiver at the end of the intervention to collect additional information relate to participation in the project.
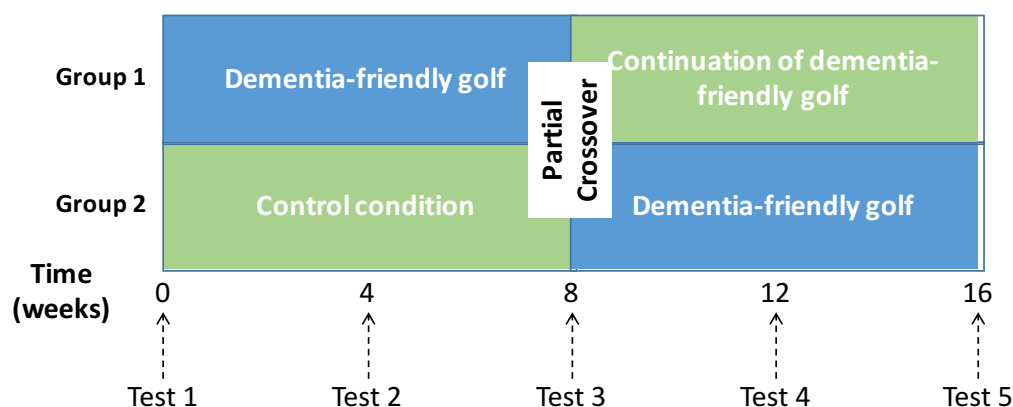
Figure 1 Experimental Design

Participants

There will be two groups of participants in the study, people with dementia and their caregivers. It can be difficult to recruit participants for research addressing dementia (Grill and Galvin 2014). To this end, a multi-pronged strategy will be used once ethical approval has been obtained. Participants will be recruited with the assistance of the Alzheimer's Society in Barnet, where the study will take place. The study will also apply for inclusion on the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Portfolio of studies, which can then be advertised using the Join Dementia Research network. Recruitment posters will also be placed in primary healthcare services in the local area who are willing to participate in the recruitment process. Finally, participants will be recruited using golf clubs in Hertfordshire. The England Golf County Development Officer will send a copy of the recruitment poster to all golf clubs in the county and ask them to display the poster in their clubhouse.

Inclusion and Exclusion Criteria

Participants will be eligible to participate in the study if they have been clinically diagnosed with dementia, regardless of the specific type of dementia. The diagnosis will be confirmed using the ICD-10 Diagnostic Criteria for Research (World Health Organization 1992). A screening test will be carried out using the timed single leg stance test, to ensure participants are able to balance sufficiently well to be able to play golf (Vellas, Wayne et al. 1997, Lowery, Cerga-Pashoja et al. 2014). People must have the capacity to give informed consent. Exclusion criteria will be people who are unable to give informed consent and without the physical capacity to play golf, as determined by a single-leg stance test of balance.

Sample size

The number of participants for this study has been limited to 24, with 12 in each group. This number has not been chosen for reasons of statistical power, but instead is due to the constraints of the golf training. A 12-person group of golfers is the maximum that can be trained by the two golf professionals available, with an additional four volunteers aiding at each session. This requirement was identified in the work at Lincoln Golf Centre, where a ratio of one buddy for every two golfers with dementia has proved successful.

The power of the study for the two groups of 12 participants was estimated using magnitude based inferences, which has been shown to outperform null-hypothesis significance testing

with respect to sample size and error rates (Hopkins and Batterham 2016). The crossover-design with 12 participants will be able to detect a standardised mean difference (SMD) of 0.8, which has been described as a moderate change (Hopkins 2006). It would require 135 subjects in each group to be able to detect an SMD of 0.2, which is equivalent to a correlation coefficient of 0.1, which has been described as the smallest worthwhile change (Cohen 1988).

Protocol

The PWD recruited for the study will undergo a golf intervention based on the pilot work developed by Golf in Society in Lincoln. The golf lessons will be run by trained golf professionals at The Shire Golf club in Barnet, Hertfordshire. All instructors have been specifically trained in working with individuals who have disabilities as part of the work of The Golf Trust, which is registered with the Charity Commission (Registered Charity Number 1172134). The club has several key requirements including being away from main roads, quiet and welcoming. The golf club has a driving range to facilitate the teaching programme and a par 3 course. The par 3 course will be used for all the lessons, which will be up to 90 minutes long, and will follow a standardised session plan. There is an indoor area available for days when weather conditions are not suited for playing golf.

In addition to the professional instructors, volunteers will be required to accompany PWD on the golf course. All volunteers will undertake dementia awareness training prior to the start of the study, as well as training in health and safety. The volunteers will be by the England Golf County Development Officer for Hertfordshire from local gold clubs.

Measurement techniques

Each assessment will involve a battery of tests for both PWD and their caregivers. With respect to the PWD group, they will be assessed for physical function, physical activity level, cognitive function, and quality of life. The caregivers will provide information related to the PWD in terms of quality of life and psychopathology in dementia. Caregivers will also provide information on themselves for quality of life and caregiver burden. Full details of the tests to be used are provided below.

Primary outcome measure

The primary outcome measure will be quality of life in PWD, which will be assessed using the DEMQOL (Smith, Lamping et al. 2005). The DEMQOL is a 28-item scale that was designed for use with all stages of dementia, and is filled in by the interviewer with the PWD.

Secondary outcome measures

Physical function will be assessed using the Short Physical Performance Battery (SPPB). The SPPB, which has been shown to be the most appropriate generic screening test in community-dwelling older people, consists of three tests that measure balance, walking speed, and muscular performance standing up from a chair (Freiberger, de Vreede et al. 2012). Recent research has shown that the SPPB can be used to measure of physical function in older adults with dementia (Fox, Henwood et al. 2014).

Physical activity levels will be recorded using the Assessment of Physical Activity in Frail Older People (APAFOP), which was validated successfully in community-dwelling older people with mild to moderate dementia (Hauer, Lord et al. 2011). The APAFOP uses more common activities in older people such as walking, standing, sitting, and lying, which are given intensity ratings and are more typical of the types of activities of older PWD.

Cognitive function will be assessed using the Montreal Cognitive Assessment (MoCA) (Nasreddine, Phillips et al. 2005). This brief screening tool was highly recommended by the Dementia Outcomes Measurement Suite (DOMS) for use as an outcome measure in studies that address potential changes in cognitive decline (Bentvelzen, Aerts et al. 2017).

Caregivers will provide assessments that relate to both themselves and the PWD they care for. Caregivers will complete the DEMQOL-Proxy, which provides an assessment of the caregiver's impression of the quality of life of the PWD they care for (Smith, Lamping et al. 2005). With respect to the quality of life of the caregiver, a recent systematic review identified that a disease-specific instrument was warranted to assess the quality of life of caregivers of PWD (Page, Farina et al. 2017). To this end, a new tool, the C-DEMQOL, has been designed specifically to assesses the quality of life of caregivers of PWD. This questionnaire is currently being developed by the Centre for Dementia Studies at the University of Brighton and will be available in time for the study to start (personal correspondence with Dr Stephanie Daley).

Caregivers will also be asked to complete the short form of the Neuropsychiatric Inventory (NPI-Q), which is a questionnaire on psychopathology in dementia (Kaufer, Cummings et al. 2000). This tool has been shown to provide a reliable assessment of neuropsychiatric symptoms and associated caregiver distress.

The total assessment of the caregivers is expected to last 60 minutes in the form of an interview. In addition to the specific questionnaires, caregivers will also be given the opportunity to discuss any issues that have arisen during the trial, with this information used for a qualitative assessment of the intervention.

Data analysis

<u>Quantitative</u>

All statistical analysis will be performed using SPSS version 25 (IBM Corp, Armonk, New York, USA). Data will be assessed for normality using the Shapiro-Wilk test owing to the small sample size. All analyses will use magnitude-based inferences, which is a method that makes inferences about the probability that the population effect is substantial or trivial, rather than null (Batterham and Hopkins 2006). Although this method is not yet widely used, it is theoretically justified in any research that involves statistical inferences (van Schalk and Weston 2016). In a recent simulation study of 500,000 randomised controlled trials, magnitude-based inferences outperformed null-hypothesis significance testing in terms of error rates, rates of publishable outcomes with suboptimal sample sizes, and publication bias from small samples (Hopkins and Batterham 2016). The results for the study will therefore be presented as effect sizes with confidence intervals, and in interpretation of the probability that the true effect is substantially positive (beneficial), substantially negative (harmful), or trivial.

<u>Qualitative</u>

Interview data will be analysed thematically to identify the key themes. The reliability and validity of theme identification will be enhanced by the use of computer-aided methods (NVivo). The overall term for the qualitative approach is constructivist grounded theory, which calls attention to the way meaning is constructed through the interaction between the participant and the researcher. The approach is well suited to research based on a collaborative ethos with participants, and is designed for topics where little is known and where pre-coded or heavily structured data collection is inadvisable.

References

Alzheimer's Society (2016). What is dementia?, Alzheimer's Society.

Barnes, D. E., W. Mehling, E. Wu, M. Beristianos, K. Yaffe, K. Skultety and M. A. Chesney (2015). "Preventing Loss of Independence through Exercise (PLIÉ): A Pilot Clinical Trial in Older Adults with Dementia." PLoS ONE **10**(2): e0113367.

Batterham, A. M. and W. G. Hopkins (2006). "Making meaningful inferences about magnitudes." Int J Sport Physiol **1**(1): 50-57.

Bentvelzen, A., L. Aerts, K. Seeher, J. Wesson and H. Brodaty (2017). "A Comprehensive Review of the Quality and Feasibility of Dementia Assessment Measures: The Dementia Outcomes Measurement Suite." Journal of the American Medical Directors Association **18**(10): 826-837.

Bossers, W. J. R., L. H. V. van der Woude, F. Boersma, T. Hortobágyi, E. J. A. Scherder and M. J. G. van Heuvelen (2015). "A 9-Week Aerobic and Strength Training Program Improves Cognitive and Motor Function in Patients with Dementia: A Randomized, Controlled Trial." The American Journal of Geriatric Psychiatry **23**(11): 1106-1116.

Cedervall, Y. and A. C. Åberg (2010). "Physical activity and implications on well-being in mild Alzheimer's disease: A qualitative case study on two men with dementia and their spouses." Physiotherapy Theory and Practice **26**(4): 226-239.

Cohen, J. (1988). Statistical Power Analysis for the Behavioral Sciences. Hillsdale, NJ, USA, Lawrence Erlbaum.

Fleiner, T., S. Leucht, H. Forstl, W. Zijlstra and P. Haussermann (2017). "Effects of Short-Term Exercise Interventions on Behavioral and Psychological Symptoms in Patients with Dementia: A Systematic Review." Journal of Alzheimers Disease **55**(4): 1583-1594.

Forbes, D., S. C. Forbes, C. M. Blake, E. J. Thiessen and S. Forbes (2015). "Exercise programs for people with dementia." Cochrane database of systematic reviews **4**: CD006489-CD006489.

Fox, B., T. Henwood, C. Neville and J. Keogh (2014). "Relative and absolute reliability of functional performance measures for adults with dementia living in residential aged care." International Psychogeriatrics **26**(10): 1659-1667.

Freiberger, E., P. de Vreede, D. Schoene, E. Rydwik, V. Mueller, K. Frandin and M. Hopman-Rock (2012). "Performance-based physical function in older community-dwelling persons: a systematic review of instruments." Age and Ageing **41**(6): 712-721.

Hauer, K., S. R. Lord, U. Lindemann, S. E. Lamb, K. Aminian and M. Schwenk (2011). "Assessment of Physical Activity in Older People With and Without Cognitive Impairment." Journal of Aging and Physical Activity **19**(4): 347-372.

Hopkins, W. G. (2006). "Sample Sizes for Magnitude-Based Inferences about Clinical, Practical or Mechanistic Significance." Medicine and Science in Sports and Exercise **38**(5): S528-S529.

Hopkins, W. G. and A. M. Batterham (2016). "Error Rates, Decisive Outcomes and Publication Bias with Several Inferential Methods." Sports Medicine **46**(10): 1563-1573.

Kaufer, D. I., J. L. Cummings, P. Ketchel, V. Smith, A. MacMillan, T. Shelley, O. L. Lopez and S. T. DeKosky (2000). "Validation of the NPI-Q, a Brief Clinical Form of the Neuropsychiatric Inventory." The Journal of Neuropsychiatry and Clinical Neurosciences **12**(2): 233-239.

Lowery, D., A. Cerga-Pashoja, S. Iliffe, I. Thuné-Boyle, M. Griffin, J. Lee, A. Bailey, R. Bhattacharya and J. Warner (2014). "The effect of exercise on behavioural and psychological symptoms of dementia: the EVIDEM-E randomised controlled clinical trial." International Journal of Geriatric Psychiatry **29**(8): 819-827.

Murray, A. D., L. Daines, D. Archibald, R. A. Hawkes, C. Schiphorst, P. Kelly, L. Grant and N. Mutrie (2017). "The relationships between golf and health: a scoping review." British Journal of Sports Medicine **51**(1): 12-19.

Nasreddine, Z. S., N. A. Phillips, V. Bédirian, S. Charbonneau, V. Whitehead, I. Collin, J. L. Cummings and H. Chertkow (2005). "The Montreal Cognitive Assessment, MoCA: A Brief Screening Tool For Mild Cognitive Impairment." Journal of the American Geriatrics Society **53**(4): 695-699.

Olsson, A., C. Lampic, K. Skovdahl and M. Engstrom (2013). "Persons with early-stage dementia reflect on being outdoors: a repeated interview study." Aging & Mental Health **17**(7): 793-800.

Page, T. E., N. Farina, A. Brown, S. Daley, A. Bowling, T. Basset, G. Livingston, M. Knapp, J. Murray and S. Banerjee (2017). "Instruments measuring the disease-specific quality of life of family carers of people with neurodegenerative diseases: a systematic review." Bmj Open **7**(3).

Primer Minister's Office (2014). UK commits to new action to find breakthrough on dementia.

Smith, S., D. Lamping, S. Banerjee, R. Harwood and B. Foley (2005). "Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology." Health Technol Assess **9**(10): 108.

van Schalk, P. and M. Weston (2016). "Magnitude-based inference and its application in user research." International Journal of Human-Computer Studies **88**: 38-50.

Vellas, B. J., S. J. Wayne, L. Romero, R. N. Baumgartner, L. Z. Rubenstein and P. J. Garry (1997). "One-leg balance is an important predictor of injurious falls in older persons." J Am Geriatr Soc **45**(6): 735-738.

Venturelli, M., R. Scarsini and F. Schena (2011). "Six-Month Walking Program Changes Cognitive and ADL Performance in Patients With Alzheimer." American Journal of Alzheimers Disease and Other Dementias **26**(5): 381-388.

Woodcock, J., O. H. Franco, N. Orsini and I. Roberts (2011). "Non-vigorous physical activity and all-cause mortality: systematic review and meta-analysis of cohort studies." International Journal of Epidemiology **40**(1): 121-138.

World Health Organization (1992). The ICD-10 classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines, World Health Organization.